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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/663,320	09/15/2000	Gavin C. Hirst	BBI-6081CP	3710

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Giulio A Deconti Jr
Lahive & Cockfield LLP
28 State Street
Boston, MA 02109

EXAMINER
KIFLE, BRUCK

ART UNIT	PAPER NUMBER
1624	28

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/663,320	Applicant(s) Hirst et al.
	Examiner Bruck Kifle, Ph.D.	Art Unit 1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 12, 2003* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-88* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-88* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *23*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/4/02 has been entered.

Claims 1-88 are pending in this application.

Claim Rejections - 35 USC § 112

Claims 1-88 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

i) Regarding "prodrugs", Applicants arguments have been fully considered but is not found persuasive. One skilled in the art can easily say whether it is a compound or a salt thereof, whereas, one skilled in the art cannot say whether a given derivative is a prodrug or not. One cannot say what it looks like. Arriving at a prodrug of a given drug is a research effort. A prodrug is arrived at after much research. A prodrug of a compound depends on the specific use and is not always the same derivative.

ii) In support of the term "substituted", Applicants again point to page 55, lines 11 to 24 of the specification. However, these line do not provide the "clear and definite definition" that Applicants say is provided. Should only these groups be contemplated, then these should be

included into the claims. One skilled in the art cannot say which substituent is intended and which one is not. Applicants state that "irrespective of the substituents on the "substituted" moiety, the compound has the claimed utility." This argument is prima facie unbelievable. Heavy metals, arsenic, etc are toxic and would not have the claimed utility. Applicants have not said whether dimers of the instant compounds, sugars, antibodies, nucleotides, are all intended or not. The term is indefinite without any support in the specification. How can one say for sure whether a given substituent is contemplated by Applicants or not?

iv) Regarding the term "heterocyclic", Applicants arguments are not persuasive. The claims need to say how many atoms make up the ring, which atoms are present and what kind of a ring (monocyclic, bicyclic, spiro, fused, bridged, saturated, etc.) is intended. The specification points to mere examples from which the generic term cannot be extrapolated. The USPTO, for example, only contemplates, O, S, N and Se as heteroatoms. Others include boron and phosphorous. Applicants need to say what is intended.

v) In claims 33 and 34 it is unclear why one would need to inhibit one or more protein kinase activity. It is unclear who needs such inhibition and what is accomplished.

Claims 33-51 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are drawn to a variety of methods.

Regarding the claims drawn to the treatment of cancer, affecting hyperproliferative disorders and affecting angiogenesis, the specification does not provide enablement for the treatment of cancer generally or affecting hyperproliferative disorders or affecting angiogenesis generally No compound has ever been found that can treat cancers generally even though massive efforts have been directed towards this end. Since this assertion is contrary to what is known in oncology, proof must be provided that this revolutionary assertion has merits. Nearly all anticancer drugs are effective against only a limited group of related cancers. Therefore, a compound effective against cancer generally would be a revolutionary exception. Applicant is asserting that he succeeded where others have failed. Where extensive efforts have all failed, it is reasonable for the Patent and Trademark Office to require proof that the claimed invention actually works for this specific utility. It is well established that a utility rejection is proper when scope of enablement is not reasonably correlated to the scope of the claims. (In re Vaeck 20 USPQ2d 1439, 1444, In re Ferens 163 USPQ 609).

In re Buting 163 USPQ 689 establishes that even clinical tests showing that a compound found to be useful in the treatment of two types of cancers was not sufficient for a much broader range.

Regarding the treatment of a cardiovascular condition, this is prima facie not enabled because "opposites" such as, hypertension and hypotension are embraced. Also, conditions which are not related are embraced by the term (e.g. leaky valve and congestive heart failure).

Similarly, there is no one thing that is an ocular condition.

Regarding the method of inhibiting one or more protein kinase activity, such a claim would read on inhibiting one or more protein kinase activity *in vitro*, inhibiting one or more protein kinase activity in mammals with below normal protein kinase activity, inhibiting one or more protein kinase activity in mammals with normal activity, or in asymptomatic mammals with up-regulated protein kinase activity. The specification fails to teach any benefit to be gained from such actions. Is extensive experimentation required on the part of a potential infringer to determine if his use of Applicants' inhibitor falls within the limitations of applicants' claim? *In re Kirk and Petrow*, 153 USPQ 48 (CCPA 1967). As the Supreme Court said in *Brenner v. Manson*, 148 USPQ at 696: "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." As U.S. Court of Customs and Patent Appeals stated *In re Diedrich* 138 USPQ at 130, quoting with approval from the decision of the board: "We do not believe that it was the intention of the statutes to require the Patent Office, the courts, or the public to play the sort of guessing game that might be involved if an applicant could satisfy the requirements of the statutes by indicating the usefulness of a claimed compound in terms of possible use so general as to be meaningless and then, after his research or that of his competitors has definitely ascertained an actual use for the compound, adducing evidence intended to show that a particular specific use would have been obvious to men skilled in the particular art to which this use relates."

Applicants are urged to rewrite these claims because of the numerous problems of patentability with these claims.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-88 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Altmann et a. (WO 97/49706). The basis of this rejection is the same as given in the previous office actions and is incorporated herein fully by reference. The reference teaches a generic group of substituted 7-amino-pyrrolo[3,2-d]pyrimidine derivatives which embraces applicants' claimed compounds. Applicants arguments is not on point. If a claim is drawn to a generic group of compounds, say, compounds 1 to 100, and if a prior art teaches or suggests, say, compound 67 (falling within the claim), then the claim is rejected. Altmann et al. teaches R_3 (corresponding to instant R_2) as "cyclo-lower hydrocarbyl" (which is defined on page 2, first line of second paragraph); the prior art R_2 corresponds to hydrogen of the instant claim; the group $-NH_2$ (corresponding to instant $N(R_3)_2$ and the overlap at both the instant and prior art R_1 is seen in the definition of R_1 on pages 1-4 of the reference.

Applicants have submitted copies of several related applications. Applicants are required to maintain a clear line of demarcation between the applications. See MPEP § 822.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruck Kifle whose telephone number is (703) 305-4484.

The fax phone number for this Group is (703) 308-4556 or (703) 305-3592. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

February 25, 2003

Bruck Kifle
Primary Examiner
Art Unit 1624